

REMARKS

Status of Claims

Claims 1, 3-11, 14-16, 19, 21-24, 31, 32 and 34-37 were pending. Pursuant to an election of species requirement, claims 3-6, 21, 22 and 31-37 have been withdrawn from consideration. Claims 1 and 31 have been amended as shown above. Thus, claims 1, 3-11, 14-16, 19, 21-24, 31, 32 and 34-37 are pending as shown above.

35 U.S.C. § 102(e)

Claims 1, 11, 14 and 19 were again rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 6,231,590 (hereinafter "Slaikeu"). Slaikeu is cited for allegedly disclosing a vaso-occlusive composition consisting of a coil and a bioactive material that comprises at least one "cytokine" such as PDGF, bFGF, VEGF and TGF-beta. (Office Action, paragraph 3).

Applicants submit that the foregoing amendments to the claims obviate this rejection.

35 U.S.C. § 102(b)

Claims 1, 7, 15, 19 and 24 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,891,192 (hereinafter "Murayama"). (Final Office Action, paragraph 4). Murayama is alleged to disclose a vaso-occlusive coil coated with a thrombus-stabilizing molecule. *Id.*, citing column 1, lines 60-62 and column 2, line 62 to column 3, line 8 of Murayama. In response to Applicant's previous response, the Final Office Action states:

The specification does not specifically define thrombus-stabilizing molecules. ... A thrombus-stabilizing molecule is not limited to ones listed in the applicant's specification. The proteins used by Murayama control the formation or development of a thrombus (column 1, lines 60-64). The control or development or formation of the thrombus includes stabilizing the thrombus. The rejection of Murayama '192 is therefore proper. (Final Office Action, paragraph 9).

The Office appears to be making an inherency argument, namely that Murayama inherently discloses thrombus-stabilizing molecules by stating that their devices "control thrombosis or effect re-embolization and healing." However, . It is well established that in order to inherently anticipate the subject matter of the claim, the allegedly inherent feature must necessarily and in all cases flow from the disclosure. *See, e.g., Ex parte Levy*, 17 USPQ2d 1461, 1464 (BPAI 1990). Inherency cannot be established by probabilities or possibilities -- the

missing descriptive material must be "necessarily present," not merely probably or possibly present, in the cited art. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 63 USPQ2d 1597 (Fed. Cir. 2002) (quoting *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)); *see, also Continental Ca Co. USA, Inc. v. Monsanto Co.* 20 USPQ2d 1746, 1749 (Fed. Cir. 1987).

Applying this case law to the pending application, Applicants submit that "controlling" thrombosis is not necessarily and inevitably stabilizing a thrombus using a thrombus-stabilizing molecule. In fact, controlling may mean initiating, promoting or even reversing thrombosis. In no way does "controlling" necessarily and in all cases mean stabilizing. Thus, the particular molecules disclosed in Murayama used to control thrombosis (*i.e.*, "cell adhesion proteins" such as collagen, fibronectin, vitronectin, laminin or fibrinogen) are not necessarily thrombus-stabilizing molecules, as claimed.

Therefore, because Murayama does not teach thrombus-stabilizing molecules *per se*, this reference cannot anticipate any of the pending claims.

35 U.S.C. § 103

The Examiner has also reiterated the obviousness rejections. First, claims 1, 7, 8, 9, 10, 23 and 24 were again rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,690,666 (hereinafter "Berenstein") in view of U.S. Patent No. 4,414,976 (hereinafter "Schwarz"). (Final Office Action, paragraph 5). In addition, claim 16 was again rejected as allegedly obvious over Slaikeu in view of U.S. Patent No. 6,256,979 (hereinafter "Nikolchev"). (Final Office Action, paragraph 6).

Applicant addresses the rejections in turn.

Schwartz

Claims 1, 7, 8, 9, 10, 23 and 24 were rejected as allegedly obvious over Berenstein in view of Schwartz. (Final Office Action, paragraph 5). Berenstein was again cited for allegedly disclosing a vaso-occlusive coil that is used with a tissue adhesive while Schwarz is cited for teaching that a surgical tissue adhesive can be made with Factor XIII, plasminogen activator or plasmin inhibitor in order to stimulate wound healing. *Id.* It is alleged that it would have been obvious to provide the device of Berenstein with the tissue adhesive of Schwartz in order to promote wound healing. *Id.* In response to Applicant's previous response, the Final Office Action states:

Applicant argues that Berenstein et al. '666 does not disclose a vaso-occlusive member and a bioactive material. Berenstein discloses both a vaso-

occlusive member (coil) and a bioactive material (adhesive). There is no language in the claim that requires the vaso-occlusive member to be assembled with the bioactive material prior to implantation. The adhesive does not need to be attached to the coil, as asserted by applicant. (Final Office Action, paragraph 10).

Contrary to the Office's repeated assertions, Schwartz is entirely silent as to tissue adhesives. The term "tissue adhesive" does not appear at column 1, lines 37-44 of Schwartz as cited in paragraph 5 of the Final Office Action. Indeed, the only mention of adhesives in Schwartz is in reference to defining the term "stent" at column 5, line 33, where it is discussed how to secure film to the framework. This is completely irrelevant to tissue adhesives as claimed and, as such, there is no motivation to combine these references. Quite simply, Berenstein's disclosure of tissue adhesives would not lead one of skill in the art to Schwartz's disclosure, which is silent as to tissue adhesives.

Nor would Schwartz's background disclosure regarding the use of TPA-expressing cells on stainless steel stents lead one of skill in the art to Berenstein's disclosure of ultrasoft vaso-occlusive devices used as a substrate for tissue adhesives. Schwartz teaches that TPA is a "therapeutic" protein. There is absolutely no mention in Schwartz that TPA (or anything else) is a tissue adhesive. Thus, there is no motivation in either Berenstein or Schwartz to combine these references as set forth in the rejection.

Moreover, Schwartz is at cross-purposes to Berenstein and the claimed subject matter. References directed to stents (Schwartz) and references directed to vaso-occlusive devices (Berenstein) are considered by the skilled artisan to be in different fields of endeavors because the former (stent technology) relates keeping vessels open while the latter (vaso-occlusive devices) relates to occluding vessels. Thus, even assuming, for the sake of argument only, that Schwartz somehow did both disclose tissue adhesives for use with implantable devices (which, for the reasons noted above, these references do not), there would still be no motivation to combine this disclosure with any vaso-occlusive device references because Schwartz's stents are used for a completely different purpose than vaso-occlusive devices.

Therefore, because there is no reason to combine Schwartz's disclosure with any references relating to vaso-occlusive devices, a *prima facie* case of obviousness cannot be established in regards to the pending claims. Accordingly, Applicant requests that this rejection be withdrawn.

Slaikeu

Claim 16 was again rejected under 35 U.S.C. § 103(a) as allegedly obvious over Slaikeu in view Nikolchev. (Final Office Action, paragraph 6). Slaikeu was cited as above for allegedly disclosing the claimed invention except for the vaso-occlusive member being micro-textured. *Id.* Nikolchev is cited for disclosing micro-texturing in order to promote tissue ingrowth and enhance the occlusion of a vessel. *Id.*


As noted above, the foregoing amendments to the claims obviate rejections based on Slaikeu. Therefore, Slaikeu, alone or in combination with Nikolchev, cannot render pending claim 16 obvious.

CONCLUSION

In view of the foregoing remarks, Applicant believes the claims are in condition for allowance and requests early notification to that effect. In addition, Applicant requests that the withdrawn claims be examined. If the Examiner believes there are any outstanding issues, she is invited to contact Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

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